

Memo to CSTE concerning IMIG supply

This is to inform you of several recent developments with respect to the manufacture and distribution of immune globulin for intramuscular injection (IMIG) and resulting changes in procedures for purchasing the product. The most notable of these developments include the re-entry of Bayer Corporation into the routine production of IMIG and the privatization of the Michigan Biologics Products Institute.

Bayer Corporation has stated its intention to regularly produce IMIG, and released its first lot in September 1997. This lot, formulated in 10 ml. vials without a preservative, was not suitable for hepatitis A postexposure prophylaxis, but was appropriate for use by persons with immune deficiency disorders who are accustomed to using IMIG. Bayer plans to produce and have ready for distribution approximately 160,000 2 ml. vials by early 1999, suitable for hepatitis A postexposure prophylaxis, and has stated its intention to distribute this product through five commercial distributors. FFF Enterprises, previously the sole distributor of IMIG during the period of product shortage, will receive approximately 20% of Bayer product.

Recently, the Michigan Biologics Products Institute (MBPI), previously associated with the State of Michigan Department of Public Health, was privatized, and is now called BioPort Corporation. BioPort does not plan to change the quantity or schedule of IMIG previously produced by MBPI.

IMIG manufactured by the Massachusetts Public Health Biologic Laboratories continues to be distributed by FFF Enterprises.

The following list summarizes which companies are now distributing IMIG from the current manufacturers.

FFF Enterprises, 1-800-843-7477

Distributes IMIG manufactured by:

Bayer Corporation

Massachusetts Public Health Biologic Laboratories

BioPort

Health Coalition, 1-800-456-7283

Chapin Medical, 1-800-221-7180

NHS, 1-800-344-6087

Nationwide, 1-800-997-8846

Distribute IMIG manufactured by:

Bayer Corporation

Alternative Site Distributors (ASD), 1-800-837-5403

BioCare Division, Blood Systems, Inc., 1-800-304-3064

Distribute IMIG manufactured by:

BioPort

It now appears that IMIG will be produced in amounts over the next 6-12 months that should adequately meet national requirements. However, the potential for significant shortages exists if unforeseen disruptions in supply of precursor material or manufacturing schedules occur. In addition, shortages could be precipitated by health departments, health care facilities, and other institutions simultaneously ordering large quantities of IMIG to replenish depleted stocks. To address the issue of possible shortages once production has increased, CDC and CSTE have secured an agreement from each manufacturer to establish an emergency reserve of IMIG that could be accessed only after consultation with CDC.

Because of the decisions of manufacturers to use multiple distributors, CDC and CSTE are no longer able to influence prioritization of IMIG distribution. However, because the potential for shortages still exists, health departments and other institutions should continue apply the previously agreed upon prioritization scheme, when appropriate, as a guideline for IMIG distribution. In addition, we request that, whenever possible, health departments spread their orders for IMIG stock over a period of 6-12 months, which would decrease the likelihood of depletion of supplies and spot shortages.

In summary:

- 1) IMIG can be purchased from any of the distributors listed above.
- 2) There is no limit on the size of IMIG orders.,
- 3) Health departments and other institutions are requested to spread orders to replenish IMIG stock over a period of 6-12 months.
- 4) CDC Hepatitis Branch epidemiologists will no longer screen large orders. As always, CDC epidemiologists will continue to be available for consultation concerning the management of hepatitis A outbreaks and exposure situations.
- 5) An emergency reserve of IMIG has been established with the three current manufacturers. State health departments unable to locate sufficient IMIG for postexposure prophylaxis after calling all current distributors, should contact the Hepatitis Branch, CDC, at 404-639-3048, for assistance in accessing the emergency reserve. Outside normal business hours, an epidemiologist can be reached by calling the CDC duty officer at 404-639-2888. The emergency reserve will be accessible only during the normal working hours of the distributors.

Please distribute this information to county health departments and other appropriate institutions in your jurisdiction. Thank you.